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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,667	04/05/2005	Vasulinga Ravikumar	ISIS-5582	4970
<div>23377 7590 09/26/2007 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891</div>				
			EXAMINER VIVLEMORE, TRACY ANN	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 09/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/510,667

Applicant(s)

RAVIKUMAR ET AL.

Examiner

Tracy Vivlemore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,11-18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

#### ***Election/Restrictions***

Applicant's comment regarding the proper status of claim 20 is acknowledged; the claim status was accurately reflected in the office action summary, due to a typographical error claim 20 was inadvertently indicated as withdrawn in this section.

Claims 19 and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 18, 2006.

#### ***Claim Rejections - 35 USC § 102***

Claims 1, 4, 11-18 and 20 rejected under 35 U.S.C. 102(b) as being anticipated by Uhlmann et al. (US 6,033,909, of record).

Claim 1 is drawn to an oligomeric compound having the structure shown in the claim, having a phosphorothioate monoester at the 5' terminus that is a phosphate attached to a 5'-thionucleotide. Claim 4 recites that one position of the modified phosphate is methylated. Claim 11 limits claim 1 by stating that R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> are each H, while in claim 12 they are each OH. Claim 13 limits claim 1 by stating at least one of R<sub>1</sub>, R<sub>2</sub> or R<sub>3</sub> may be an optionally protected substituent group, while claim 14 requires at least one optionally protected substituent group. Claim 15 limits claim 1 by stating that each X<sub>2</sub> is S. Claim 16 limits claim 1 by reciting several possible heterocyclic base

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moieties that may exist within the oligomeric compound. Claims 17 and 18 limit claim 1 by stating the length of the oligonucleotide is between 8 and 30 or 15 and 25. Claim 20 is drawn to a composition comprising the oligomeric compound of claim 1 with a pharmaceutically acceptable carrier or diluent.

Uhlmann et al. disclose oligonucleotides having the formula shown in claim 1. In this formula, the internucleotide linkages can be mono- or diphosphorothioate, meeting the specific limitations of claims 1 and 15. The V at the 5' position of the ribose can be O or S and the terminal R<sup>1</sup> can be a phosphate group, which is the equivalent of the structures of claim 1. The Z position of the terminal phosphate groups can be C<sub>1</sub>-C<sub>18</sub> alkyl, meeting the limitation of claim 4. In the oligonucleotides disclosed by Uhlmann et al., R<sup>2</sup> can be hydrogen, hydroxyl or other substituents, meeting the limitations of claims 11-14. Position B is disclosed as being a conventional nucleotide base, meeting the limitations of claim 16. The oligonucleotides of Uhlmann et al. are 2-101 nucleotides in length, meeting the limitations of claims 17 and 18 and are disclosed in claim 9 as compositions with pharmaceutically acceptable carrier or diluent, meeting the limitations of claim 20.

Thus, Uhlmann et al. disclose all limitations of and anticipate claims 1, 4, 11-18 and 20.

### ***Response to arguments***

Applicants traverse the rejection over Uhlmann et al. by asserting the Office Action mischaracterizes the patent's disclosure, noting that the reference discloses oligonucleotides with 3' terminal phosphates. Applicants submit that because T<sub>2</sub> is recited as being a hydroxyl, a protected hydroxyl, an oligonucleotide or an

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oligonucleoside, the instant claims recite an oligomeric compound without a phosphate group at the 3' position. This argument is not persuasive because the instant claims are not limited in the way applicants assert, because the claims recite the T<sub>2</sub> position can be an oligonucleotide. The definition of T<sub>2</sub> as an oligonucleotide embraces oligonucleotides with and without a 3' terminal phosphate; therefore the Uhlmann et al. reference anticipates the claims.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz, can be reached on 571-272-0763. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

TV  
September 20, 2007

Tracy Vivlemore  
Examiner  
Art Unit 1635



RICHARD SCHNIZER, PH.D.  
PRIMARY EXAMINER